



# Access to Medicine: Pharmaceutical Patents and Public Health Needs Under the WTO Framework

## Citation

Kuanling Liu, Access to Medicine: Pharmaceutical Patents and Public Health Needs Under the WTO Framework (April 2008).

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**ACCESS TO MEDICINE:**

**PHARMACEUTICAL PATENTS AND PUBLIC HEALTH NEEDS UNDER THE WTO FRAMEWORK**

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Submitted to Professor Peter Hutt in Fulfillment of the Food and Drug Law Course Paper and

LL.M. Written Work Requirement

April 24, 2008

### Abstract

Many people, particularly in developing countries, die from curable or manageable diseases without access to medicine. After the TRIPS Agreement was brought into force, access to medicine in developing countries became worse and even deteriorated development. To solve the controversy in interpreting the TRIPS Agreement and the resulting public health crises, the Doha Declaration was adopted, recognizing the flexibilities of the TRIPS Agreement as effective and vital manners to promote access to medicines. However, there are still many difficulties encountered by developing countries in full implementation of the Doha Declaration. Therefore, this paper aims to reexamine and reaffirm access to medicine as an international human right, claiming it should be accommodated under the WTO framework, and also proposes several possible solutions to advance the accessibility of medicine.

## I. Introduction

The public health crises mainly confronted by developing countries are involved multi-dimensional of problems, particularly with regard to the conflict between access to medicine and the pharmaceutical patent regime. Following the Agreement on Trade-related Intellectual Property Rights (the TRIP Agreement), which links trade and the intellectual property rights, the problem of access to medicine in developing countries has worsened and become more complex and worse. When developing countries try to struggle and fight for its public health needs under the World Trade Organization (the WTO) framework, they are met with the pressure and obstacles set by the developed world and its pharmaceutical industry that assert patent protection serves as an incentive for invention. Developing and developed countries perceive the TRIPS Agreement in different ways, thereby causing conflicts among nations and preventing appropriate measures from reaching public health emergencies. Therefore, it is beneficial to delve into this study by exploring the interrelationships among the underlying value of pharmaceutical patent, access to medicines, and the advancement of public health; thus providing grounds to figure out a way to balance the interpretation of the TRIPS Agreement and other documents under the WTO framework, in particular, to ensure access to medicine without sacrificing incentives to innovation. Furthermore, the case that the Taiwanese government approved the compulsory license of Tamiflu in 2005, which was the first compulsory license of Tamiflu granted in the world, when the possibility of an Avian Influenza pandemic, also inspired me to engage in this study to explore the conflict between pharmaceutical patent rights and public health needs.

Part II of this paper gives an overview of how the public health needs are impacted by access to medicine. First, I review the global health crises in the 21<sup>st</sup> century, pointing out the importance of access to medicine, and then indicate that the high cost of drugs price is a major barrier for developing countries to access medicine. In Part III, I probe into the interrelationship between pharmaceutical patent protection and access to medicine. Beginning with a review of the history of patent law development, particularly with an emphasis on the patentability of pharmaceutical products, this paper suggests that patents are granted at the discretion of the national authorities as a mechanism to promote development of country. Then I review the international patent law before and after the TRIP Agreement was introduced, examining the flexibilities – in particular the parallel imports and compulsory licensing under the TRIPS Agreement – used to accommodate the public health needs to access to medicine. Part IV of this paper observes the difficulties experienced by developing countries in adopting the TRIPS flexibilities on pharmaceutical patents, the efforts made in the Doha Declaration attempting to resolve these difficulties, and also gives an evaluation of the Doha Declaration. In Part V, I first locate the right of access to medicine under the international human right framework, and secondly claim that, under such framework, the human right of access to medicine surpasses pharmaceutical patent holder's right in public health emergencies. Third, I propose possible solutions to the global public health concerns of access to medicine.

By investigating the public health crises mainly faced by developing countries, we can observe the intense conflicts between different rights and obligations. While the topics mentioned in this paper have long

been debated among developing and developed countries, this paper intends to deliberate the issue from a more fundamental perspective, and tries to propose possible solutions while serving as a preliminary research in this regard for future study.

## II. How Does the Access to Medicine Influence Public Health Needs?

### 1. Global Public Health Threats in the 21<sup>st</sup> Century

In addition to the spread of food borne illnesses and environmental disasters, epidemic-prone diseases pose a major threat to people's health in the 21<sup>st</sup> century.<sup>1</sup> AIDS, malaria, and tuberculosis have been widely known to cause high mortality rates<sup>2</sup> in the developing and least developed countries in Africa, South America and Asia before this century. Some newly emerging diseases in the 21<sup>st</sup> century, such as Severe Acute Respiratory Syndrome (SARS)<sup>3</sup> and avian influenza in humans, even fuel the global concern for the battle against infectious diseases. With the mobility and interdependence of countries in today's world, the speed in which diseases spread is faster than ever before.<sup>4</sup>

Take the AIDS prevalence as an example<sup>5</sup> for illustrating an epidemic's impact on the socio-economic

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<sup>1</sup> World Health Organization, *The World Health Report 2007: A safer future: global public health security in the 21st century*. Geneva: World Health Organization (2007), <http://www.who.int/whr/2007/en/index.html>

<sup>2</sup> Infectious diseases claim more than 10 million people's life each year, and among them, more than 90 percent of death happens in the developing world. See Ellen't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 Chi. J. Int'l L. 27, 1 (2002).

<sup>3</sup> When SARS swept away East Asia in 2003, I was in Taiwan and witnessed the SARS panic. This experience also aroused my interest in conducting this study in the area of public health law.

<sup>4</sup> "Since the 1970s, newly emerging diseases have been identified at the unprecedented rate one or more per year. There are now nearly 40 diseases that were unknown a generation ago. In addition, during the last five years, WHO has verified more than 1100 epidemic events worldwide." *Supra* note 1, at x.

<sup>5</sup> On account of the HIV/AIDS pandemic, it is currently the most representative example stating the conflict between citizens/patients

aspects of a society: in 2007, there are around 33.2 million people worldwide, including 2.5 million children, infected with AIDS, and 2.1 million of whom, including 330,000 children, died of this epidemic. Geographically, sub-Saharan Africa has just over 10 percent of the world's population<sup>6</sup>, but it has always been the most infected area. 22.5 million people, which is 68% of all HIV positive patients, living with AIDS are in this region, making up over three-fourth of all AIDS deaths in 2007.<sup>7</sup> The HIV/AIDS threat has impeded regional economic growth and ruined human capital because many HIV positive patients are young adults who are in the productive age for their households. Thus their infectious status leads to huge demands of medical treatment, while their premature mortality leads to a small number of the labor force and leaves the expected pay-off burden to their children as the mechanism to transmit knowledge and abilities from one generation to another is strongly weakened through the loss of income, expense on healthcare and burial of the parents.<sup>8</sup> Besides its impact on family, nationally, the decreasing output and increasing expenditure on healthcare are obstacles for the government to manage its resources, let alone to get rid of its poor plight or to shorten the difference among countries and regions. The AIDS pandemic has become a development crisis, rather than just a public health issue. If the response to the epidemic is delayed, future generations have to

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and access to medicine. It is not the only one case for sure. See HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 15 (2007).

<sup>6</sup> World Bank, *HIV/AIDS in Africa – ACTAfrica*,

<http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/AFRICAEXT/EXTAFRHEANUTPOP/EXTAFRREGTOPHIVAI DS/0,,contentMDK:20411613~menuPK:717155~pagePK:34004173~piPK:34003707~theSitePK:717148,00.html>, (last visited March 24, 2008).

<sup>7</sup> UNAIDS, WHO, *2007 AIDS Epidemic Update* (2007),

<http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2007/>

<sup>8</sup> Clive Bell, Shantayanan Devarajan, Hans Gersbach, *"The long-run economic costs of AIDS: theory and an application to South Africa"*, World Bank Policy Research Working Paper No. 3152 (2003),

[http://www1.worldbank.org/hiv\\_aids/docs/BeDeGe\\_BP\\_total2.pdf](http://www1.worldbank.org/hiv_aids/docs/BeDeGe_BP_total2.pdf). See also Robert Greener, *AIDS and macroeconomic impact*, in S. Forsyth (ed.): *State of The Art: AIDS and Economics*. IAEN, 49–55 (2002).

suffer from an even worse collapse.<sup>9</sup>

Not only do people living in the developing and least developed countries are suffered from the infectious diseases that deteriorate even their poverty and living environment, but some people in the developed countries are now under epidemic health risks. Anthrax attacks to the United States in 2001 emphasized the importance of coping with countermeasures to the issue. Developed countries can no longer stand aside and put themselves out of stormy epidemics.

## 2. The Right to Access Medicines

Access to medicine plays a critical role in improving public health because modern medical science heavily relies on medicine or vaccination to cure or to prevent diseases. There are effective medical treatments for most of the leading infectious diseases, including acute respiratory infections, HIV/AIDS, malaria, tuberculosis and the complications of measles.<sup>10</sup> But most of time, people in the developing world lacking health care infrastructure die for having no access to medicines.

However, not every kind of medicine can be legitimately claimed as a right to access medicine. According to the social value of medicine, it can be divided into three categories – essential medicine, new medicine, and medicine that does not yet exist. The WHO defines essential drugs as “those that satisfy the

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<sup>9</sup> UNAIDS, *Supra* note 7.

<sup>10</sup> WHO, *WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy- 2000-2003*, Geneva: WHO, <http://www.who.int/medicinedocs/en/d/Jwhozip16e.4#Jwhozip16e.4> (last visited March 24, 2008).



priority health care needs of the population,” and most of them are off-patent.<sup>11</sup> Access to essential medicine is particularly important in the issue and can be claimed as a right because it means that such effective and safe drugs are greatly related to public health. Furthermore, essential medicine can be obtained with affordable prices, sustainable financing, and reliable health and supply systems since it is easier for medical personnel to predict its side effects and interactions with other drugs, to ensure its quality. Therefore, it is significant for national drug policy to afford essential medicine<sup>12</sup> to the needy, especially the diseases related to poverty, and to ensure quality, safety, and efficacy.<sup>13</sup> It is estimated, however, that one-third of the population lack access to essential drugs, over one-half of whom are in the most impoverished area in Africa and Asia.<sup>14</sup> Thus, the World Health Organization (WHO) set up a list of essential medicines<sup>15</sup> in 1977, as one of WHO’s primary health care strategies and updates the list every two years by an expert committee in an effort to provide a model for countries to adapt to their needs, which is especially valuable for countries with scarce resources to access the best medicine within available resources.<sup>16</sup>

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<sup>11</sup> ALYNA C. SMITH, *INTELLECTUAL PROPERTY RIGHTS AND THE RIGHT TO HEALTH: CONSIDERING THE CASE OF ACCESS TO MEDICINES, ETHICS AND LAW OF INTELLECTUAL PROPERTY: CURRENT PROBLEMS IN POLITICS, SCIENCE AND TECHNOLOGY* 53 (Christian Lenk, Nils Hoppe, Roberto Andorno eds., 2007)

<sup>12</sup> The definition of essential drugs: “Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times, in adequate amounts and in the appropriate dosage forms.”, *The Use of Essential Drugs*, 6th Report of the Expert Committee, WHO Technical Report Series 850. In April 15-19, 2002, in WHO’s 12<sup>th</sup> Expert Committee on the Selection and Use of Essential Medicines Meeting, the name “essential drugs” is changed into “essential medicines”, WHO, 12<sup>th</sup> Expert Committee on the Selection and Use of Essential Medicines Meeting, 2002, <http://mednet3.who.int/EMI/expcom/expcom12/expertrecomm.htm> (last visited March 25, 2008).

<sup>13</sup> WHO, *Progress in essential drugs and medicines policy*, 1998-1999, WHO, Geneva, <http://www.who.int/medicinedocs/en/d/Jh2950e> (last visited March 24, 2008).

<sup>14</sup> WHO, *WHO Medicine Strategy: 2000-2003*, Geneva: WHO, <http://www.who.int/medicinedocs/fr/d/Jwhozip16e.5.2>

<sup>15</sup> WHO, *WHO Model Lists of Essential Medicines*, <http://www.who.int/medicines/publications/essentialmedicines/en/> (last visited March 25, 2008)

<sup>16</sup> WHO, *supra* note 11

### 3. Drug Price as a Key Barrier to Access to Medicine for Developing Countries

*“The poor cannot afford expensive medicines. Keeping an AIDS patient alive for a year can cost up to \$15,000— 24*

*times the average annual income in Zimbabwe, where one in four adults is HIV-positive.”*

*- Mike Moore, Former WTO Director-General*

There are two kinds of difficulties faced by developing countries in the outbreak of public health crisis – one is the difficulty of access to medicine; the other the difficulty of developing new drugs while the existing drugs are not effective enough.<sup>17</sup>

In the first difficulty, it is known that the worldwide distribution of epidemics is not equal. It tends to be centralized in the developing or least developed areas yet the same region are also the most lack in drug access also congregated in the same region. Though there are many factors relevant for patients to have access to the medicine needed, including the rational choice and use of drugs, continuously abundant funds, reliable drug supply systems etc. Here we only discuss the factors related to the TRIPS Agreement that hinders the access to medicine to developing countries, that is, the high price of drugs and the low income of the people.<sup>18</sup>

First, the high price of medicine is due to the specialty of the pharmaceutical industry. The pharmaceutical industry has complex industrial structure and highly professional division of labor. It requires not only long research and developing periods but also a great deal of capital. The risk and rate of return are

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<sup>17</sup>YA-WEN LEI, KAIFA ZHONG GUOJIA ZAIYU MAOYI YOUGUAN ZHI ZHIHUICAICHANQUAN XIEDINGXIA YAOPIN QUDE KUNNAN ZHI YANJIU: XUNQIU KEYI JIANGU HUIYUAN GONGGONGJIANKANG ZHENGCE DE GUOJI ZHIHUICAICHANQUAN TIZHI [Dilemma of Access to Medicines Faced by Developing Countries under the TRIPS Agreement - seeking an international intellectual property regime beneficial for the public health policy of members] 25, (unpublished M.A. thesis, National Chiao Tung University, 2004).

<sup>18</sup> *Id.*

both very high. Furthermore, given that drugs directly affect human's safety and health, there is a strict premarket review of new drugs by the government. For instance, in the United States, it takes about 10 to 15 years for a new drug to develop from the initial chemical analysis stage through the obtainment of FDA's approval as a new drug.<sup>19</sup> Therefore, drug price reflects its development cost in both time and money. In low income economies,<sup>20</sup> the expenditure of high price drugs accounts for a large percentage of family burdens and is never affordable. People usually have no choice but to give up medical treatment. Moreover, when the spokespersons of the pharmaceutical industry or some research centers refer the high cost of drugs to their research and development cost in order to justify high drug prices and strong drug patents, readers should be careful about how the figures are computed, including the inherent drawbacks of studies,<sup>21</sup> and the representative of "the average development cost of drugs"<sup>22</sup>.

### III. The Relationship Between Pharmaceutical Patents and Access to Medicine

When confronting the public health crisis and difficulty in access to medicine, in the developing world, many non-government organizations and human rights advocates assert that pharmaceutical patents is the

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<sup>19</sup> PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW* 577 (2007)

<sup>20</sup> The main criterion for World Bank's country classification of economies is gross national income (GNI). According to the 2006, low income economies are referred to those GNI per capita \$905 or less. The World Bank, Country Classification, <http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20420458~menuPK:64133156~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html> (last visited March 25, 2008)

<sup>21</sup> See MERRILL GOOZNER, *THE \$800 MILLION PILL. THE TRUTH BEHIND THE COST OF NEW DRUGS* (2004). See also PUBLIC CITIZEN, *AMERICA'S OTHER DRUG PROBLEM: A BRIEFING BOOK ON THE RX DRUG DEBATE* (2002).

<sup>22</sup> Many drugs are funded by public funding in the process of basic research and clinical testing. See J.A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, *Journal of Health Economics* 10, 107-142 (1991); See also SIGRID STERCKX, *LACK OF ACCESS TO ESSENTIAL DRUGS: A STORY OF CONTINUING GLOBAL FAILURE, WITH PARTICULAR ATTENTION TO THE ROLE OF PATENTS, ETHICS AND LAW OF INTELLECTUAL PROPERTY: CURRENT PROBLEMS IN POLITICS, SCIENCE AND TECHNOLOGY* 184-185 (Christian Lenk, Nils Hoppe, Roberto Andorno eds., 2007).

major cause of the high prices of drugs and are therefore, the obstacles to access to medicine. Nevertheless, some developed countries and pharmaceutical companies oppose this connection, arguing that granting drug patents does not lead to price increasing.<sup>23</sup> In this section, it is necessary to first understand the purpose and nature of patent law and its position under World Trade Organization (hereinafter: WTO) in order to probe into the correlation of patents on pharmaceuticals under the TRIPS Agreement and accessibility of drugs in developing countries.<sup>24</sup>

## 1. Overview of the Patent Law

### A. Patent Law history

This survey of the history of patent law is intended to demonstrate that for a long time, patents have been granted at the discretion of the national authorities as a mechanism to advance national development, not as a natural law property right of inventor. Furthermore, the legislators have tried to balance encouraging creativity with reducing drawbacks, such as higher prices.<sup>25</sup>

Early in the ancient Greece, inventions were encouraged to be brought into the society and inventors

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<sup>23</sup> Rozek RP, Berkowitz R., *The Effects of Patent Protection on the Prices of Pharmaceutical Products*, White Plains, NY: National Economic Research Associates (1998). Another study criticizes that this study does not new innovative drugs' prices. Since the pharmaceutical company feels certain with the drug patent protection, it has advantages in bargain prices with the public health authority. Additionally, with the liberalization of international drug trade, pharmaceutical companies are less likely to cut down drug' prices to less developed countries for fear of parallel imports. Consequently, it poses risks to access to medicine. See Bernard Pécoul et al, *Access to Essential Drugs in Poor Countries: A Lost Battle?*, Journal of the American Medical Association, Vol 281, No. 4, 366 (1999).

<sup>24</sup> Lei, *Supra* note 17, at 36

<sup>25</sup> Hestermeyer, *supra* note 5, at 18.

would be given a prize reward or exclusive right as an incentive for the contribution.<sup>26</sup> The first true patent was issued in 1421 in Renaissance Italy, and the first true patent statute was enacted in 1474 by the Venetian Republic, seeking technological advancement and knowledge importation<sup>27</sup> by granting patents or importation license for the common good.<sup>28</sup> In order to encourage more people to invent ingenious devices, others were not allowed to make the same or similar devices without the patentee's consent for ten years.<sup>29</sup> During 15<sup>th</sup> and 16<sup>th</sup> centuries, England was in general actively granting importation franchises and monopolistic privileges.<sup>30</sup> However, patent practice was abused in reign of Elizabeth I (1558-1603) and James I (1603-1625). Not until in 1623 did Parliament pass the Statute of Monopolies, the first English patent statute governed English patent law for more than 200 years, to reflect a general skepticism about monopolies and to confirm the common law view that patents should not be tolerated if not serving the public good.<sup>31</sup> During the 17<sup>th</sup> and 18<sup>th</sup> centuries, it become a common requirement to submit the *specification*, “a full description of the invention and its operation which would show the scope of the patent”<sup>32</sup>, for the purpose of knowledge dissemination by the inventor to make it easier for others to build upon and enhance knowledge;<sup>33</sup> the law no longer concerned merely the introduction of inventive devices.<sup>34</sup> This specification requirement was included

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<sup>26</sup> DONALD CHISUM ET AL, PRINCIPALS OF PATENT LAW 7 (2004).

<sup>27</sup> Hestermeyer, *supra* note 5, at 22.

<sup>28</sup> *Id.* at 10, 11.

<sup>29</sup> Hestermeyer, *supra* note 5, at 22.

<sup>30</sup> Chisum, *supra* note 26, at 13. *See also* BRUCE BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 34-35 (1967).

<sup>31</sup> *Id.*, at 15. *See also* Hestermeyer, *supra* note 5, at 23. *See also* CHRISTINE MACLEOD, INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM I, 17-19 (1988).

<sup>32</sup> Bugbee, *supra* note 30, at 41-42; *See also* GERARD DOORMAN, PATENTS FOR INVENTIONS IN THE NETHERLANDS DURING THE 16<sup>TH</sup>, 17<sup>TH</sup> AND 18<sup>TH</sup> CENTURIES 22-23 (1942).

<sup>33</sup> *See also* H. DUTTON, THE PATENT SYSTEM AND INVENTIVE ACTIVITY DURING THE INDUSTRIAL REVOLUTION 1750-1853 (1984)

<sup>34</sup> Chisum, *supra* note 26, at 15

and become a standard feature in the first US Patent Act, the Patent Act of 1790, based on the power that the US Constitution had granted to Congress to “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>35</sup> Under US Patent Act of 1790, it remained a discretionary affair to grant patents if it is deemed to be sufficiently useful and important, not that it has to be granted. However, following Locke’s natural law theory arguing that every man has a natural right in the fruit of his labor, intellectual property is equivalent to other kind of property. Patents at that time began to be granted as a right, notwithstanding that this natural law rationale is now almost universally rejected at the national level.<sup>36</sup> The US Supreme Court interpreted US Patent Act of 1793 to be that an inventor has a right to be granted a patent. In the 19<sup>th</sup> century, many countries established its patent system, but, in the second half of 19<sup>th</sup> century, it was confronted by an anti-patent free-trade movement. To its national development purpose, some countries decided not to adopt patent laws or establish exceptions for patentability.<sup>37</sup>

### B. The Patentability of Pharmaceutical Products

Modern US patent law grants patents on “any new and helpful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>38</sup> Pharmaceutical products are chemical

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<sup>35</sup> U.S. CONST. art. I, §8, cl 8.

<sup>36</sup> Hestermeyer, *supra* note 5, at 38.

<sup>37</sup> *Id.*, at 26-27.

<sup>38</sup> 35 U.S.C. §101.

compounds, categorized as “composition of matter” and therefore eligible for patent protection.<sup>39</sup>

Pharmaceutical industry and chemical industry are generally acknowledged as industries that mostly relied on patent protection for the large amount of labor and funds invested in research and development. New drugs, mainly profitable from patents in the monopoly market though the distribution of new drug manufactures, are not equally distributed as they are principally located in the United States.

For fear of the negative effects on public health, however, many countries, such as France, Germany, Japan, Switzerland, Norway, and other developed countries, did not adopt patent protection for pharmaceutical products until the second half of the 20<sup>th</sup> century. An alternative for countries in the face of public health crisis regarding to pharmaceutical patentability is to grant compulsory licenses whenever needed.

## 2. International Patent Law Prior to the TRIPS Agreement

Due to the disharmony of national patent laws, many problems arose with the cross-border trade that sprang up in the 19<sup>th</sup> century. Prior to the TRIPS Agreement, only a small number of bilateral treaties served as remedies to the international patent law inconsistency. In 1873, the international exhibition of inventions in Vienna marked a decisive victory for international patent harmonization. This conference and subsequent conferences resulted in 1883 diplomatic conference in Paris, adopting the first international agreement regarding patent protection. The Paris Convention for the Protection of Industrial Property (Paris Convention),

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<sup>39</sup> Hestermeyer, *supra* note 5, at 28.

ratified by 129 states although some developing countries were reluctant to sign,<sup>40</sup> came into effect on July 7, 1884 and has been revised a few times.<sup>41</sup> Nevertheless, the Paris Convention does not establish substantive standards for industrial property to which members must adhere. Patent laws still diverged in member nations and as long as it abided by the premise of national treatment granted by the Paris Convention, a member state is free to enact statutes with fewer or more intellectual property protection.<sup>42</sup> Additionally, disputes between member nations are set to be settled by the International Court of Justice (ICJ) under Article 28 of the Paris Convention, but many member states do not recognize ICJ to have jurisdictions in their countries. Even for member states that recognize its jurisdiction, ICJ rulings are not executed. As a result, infringement is unable to be remedied.<sup>43</sup> The World Intellectual Property Organization (WIPO) was created in 1967, later becoming a specialized agency of the United Nations, with a purpose “to encourage creative activity, [and] to promote the protection of intellectual property throughout the world,”<sup>44</sup> now administered the Paris Convention and other treaties.<sup>45</sup> “[D]espite WIPO’s efforts to promote international comity with respect to IPR protection, the level of harmonization across countries achieved by the mid-1980s remained limited.”<sup>46</sup> The problem of a

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<sup>40</sup> *Id.* at 39.

<sup>41</sup> PAUL GOLDSTEIN, INTERNATIONAL INTELLECTUAL PROPERTY LAW 299 (2001).

<sup>42</sup> MICHEL RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY 104 (1998).

<sup>43</sup> Evelyn Su, *The Winners and the Losers: The Agreement on Trade-related Aspects of Intellectual Property Rights and Its Effects on Developing Countries*, 23 *Hous. J. Int’l L.* 169, 179-180 (2000).

<sup>44</sup> Convention Establishing the World Intellectual Property Organization, signed at Stockholm on July 14, 1967, Preamble, second paragraph..

<sup>45</sup> L. Danielle Tully, *Prospects For Progress: The Trips Agreement And Developing Countries After The Doha Conference*, 26 *B.C. Int’l & Comp. L. Rev.* 129, 132 (2003).

<sup>46</sup> Carlos A. Primo Braga, *Trade-Related Intellectual Property Issues: The Uruguay Round Agreement and Its Economic Implications* 3 (1995) (paper presented at The Uruguay Round and the Developing Economies-A World Bank Conference)



lack of coordination of every aspect of national patent laws remained<sup>47</sup> and thus resulted in a lack of intellectual property protection. The weak protection of intellectual property, that is, allowing counterfeits, enabled many developing countries to have huge economic growth at that time.<sup>48</sup> However, since most patents are owned by companies from developed countries, these countries were seeking stronger protections over patents, claiming that the little or none patent protection in developing countries had formed barriers to international trade and made no contribution to, but profited from, knowledge development.<sup>49</sup> Though “piracy” was legal within these weak intellectual property protection countries, the developed country industries suffered from a significant loss. On the other hand, from developing countries’ perspective, the stronger patent protection – some were made by their former colonial masters – was not consistent with the level of their economic development.<sup>50</sup> Moreover, free riding technology from abroad, would foster the technology development of these countries. To date, this North-South debate continues.

Therefore, with the failure of WIPO functions, the United States and European Communities imposed unilateral trade sanctions against individual developing countries, especially the United States’ use of section 301 and special 301 in the areas of intellectual property laws of the US Trade Act of 1974 to advance US interest, where it was perceived as unjustifiable, unreasonable, discriminatory, or inconsistent with trade

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<sup>47</sup> Aspects that are lack of consistency include: minimum of the patent term, over-liberal compulsory licensing regulations, areas of patentability. See Hestermeyer, *supra* note 5, at 37. See also Frederick M Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 Vand J of Transnat’l L. 689, 703 (1989)

<sup>48</sup> N Kumer, *Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries*, Commission on Intellectual Property Rights Study Paper 1b, 4 (2002)

<sup>49</sup> Lei, *supra* note 17, at 51. Hestermeyer, *supra* note 5, at 37.

<sup>50</sup> Sterckx, *supra* note 22, at 186.

agreements.<sup>51</sup>

Meanwhile, the developed world does not give up seeking a multilateral intellectual property agreement to unify the intellectual property system. In the linkage between intellectual property rights to international trade, the United States and other developed countries looked to include intellectual property rights in the General Agreement on Tariffs and Trade (GATT).<sup>52</sup> They had three major concerns: first, to enlarge their trade worldwide by prevailing international protection of intellectual property; second, to set up an effective mechanism to implement and settle disputes on intellectual property; third, to ensure that other countries follow developed country model, extending intellectual property rights to new innovation; thus earning profit therein.<sup>53</sup>

Since the GATT contains no direct provisions on intellectual property rights, and the most related provision is Article XX(d), later in the Uruguay Round, the intellectual property rights were finally included in trade relations mainly under the pressure from the United States,<sup>54</sup> despite the strong objection from developing countries. A new agreement, the Final Act of the Uruguay Round and the Marrakesh Agreement Establishing the World Trade Organization (hereinafter: the WTO Agreement), was signed by the end of the Uruguay Round in 1994. The Round transformed GATT into WTO.

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<sup>51</sup> Hestermeyer, *supra* note 5, at 39-40.

<sup>52</sup> Abbott, *Supra* note 47, at 695-96; General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

<sup>53</sup> Jonathan Michael Berger, *Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity*, 17 Conn. J. Int'l L. 157 (2002).

<sup>54</sup> Ryan, *supra* note 42, at 108

### 3. The TRIPS Agreement

The WTO Agreement consists of six main parts: the Multilateral Agreements on trade in goods including the GATT 1994, which includes the GATT 1974, and the Trade Related Investment Measures, trade in services (the General Agreement on Trade in Services (GATS)), intellectual property rights (the TRIPS Agreement), dispute settlement (Dispute Settlement Understanding (DSU)), and Reviews of governments' trade policies (TPRM). These agreements are all enforced by a stronger dispute settlement body, made up of all member governments. If a trade dispute arises, the complainant can create a panel and the panel report can only be rejected when everyone agrees not to adopt it. Appeals against a panel report can be filed with a standing Appellate Body, which is composed of seven members appointed by the Dispute Settlement Body to serve for four-year terms.<sup>55</sup> The WTO's mechanism for dispute settlement makes the trade function more secure than before, remedying the enforcement defects in the international intellectual property system.<sup>56</sup>

On the other hand, the negotiation process was full of hardships as the TRIPS Agreement only shifted the mode of argument between developed and developing countries. Developed countries, such as the United States and Japan, sought a comprehensive agreement on intellectual property standards in order to protect the incentive for innovation while developing countries argued that the mandate only covered "trade-related" intellectual property rights, referring to the WIPO for the comprehensive intellectual property forum.<sup>57</sup>

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<sup>55</sup> WTO, Understanding the WTO: Settling Disputes, A Unique Contribution, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/displ\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/displ_e.htm)

<sup>56</sup> Hestermeyer, *supra* note 5, at 45-46.

<sup>57</sup> *Id.*

However, confronted with the developed countries' contention of the "trade-related" character of all intellectual property law, critics argue that similar effects can be claimed with many domestic regulations.<sup>58</sup>

The inclusion of intellectual property law into international trade law, the GATT/WTO system, is not strongly grounded and served the interest of developed countries.<sup>59</sup> Even though the developing countries finally gave up resisting the agreement, there were still many problems that needed to be addressed in the negotiations, such as the patentable subject-matters, non-discrimination, patent term, and burden of proof to compulsory licensing.<sup>60</sup> After the implementation of the TRIPS Agreement had been implemented for years, its consequences became clear. Many developing countries' dissatisfaction to the Agreement revived even more strongly, thereby contending the coercive character of the treaty.<sup>61</sup>

#### 4. Pharmaceutical Patents under the TRIPS Agreement

In the process of the TRIPS Agreement negotiations, developing countries demanded their exclusion from pharmaceutical patent protection since patent protection should not outweigh the public health needs.<sup>62</sup> However, as a result of the discussion, Article 27(1) of the TRIPS Agreement implies that patent must be granted "for any inventions, whether products or processes, *in all fields of technology*...", and that patent rights must be enjoyable "*without discrimination* as to ... the field of technology." Therefore, since TRIPS is binding

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<sup>58</sup> Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Meeting of the Negotiating Group of 23 September 1987*, MTN.GNG/NG11/3 (1987).

<sup>59</sup> Hestermeyer, *supra* note 5, at 46.

<sup>60</sup> T Cottier, *The Prospects for Intellectual Property in GATT*, 28 Common Market Law Review 383, 405 (1991); *Id.* at 47.

<sup>61</sup> *Id.* at 48.

<sup>62</sup> *Id.* at 47.

on all Members, they are all obligated to grant pharmaceutical product patents.

Nevertheless, the wording of the Agreement allows some degree of manipulation to accommodate of the public health concerns.<sup>63</sup> The TRIPS Agreement Article 1.1 provided that, “Members should give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”<sup>64</sup> In short, it aims to impose a minimum standard to patent right protection on member nations.<sup>65</sup>

### 5. Flexibilities Under the TRIPS Agreement

As Article 30 of the TRIPS Agreement states, “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties,” the wording of this article is very general and imposes no substantive limitation to the content of exceptions. Thus, Members are entitled to decide the types

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<sup>63</sup> *Id.* at 49.

<sup>64</sup> TRIPS, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round Vol. 1c. 31, 33 I.L.M. 81 (1994).

<sup>65</sup> SUDIP CHAUDHURI, THE WTO AND INDIA’S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 62 (2005).

and scopes of limitations,<sup>66</sup> accommodating Members' policy and implementation considerations. In this study, the right to access to medicine would be used as an argument in the interpretation of the flexibilities.<sup>67</sup>

### A. Parallel Imports

The meaning of parallel imports is that the patented product placed in a country by the patent holder or with its consent is imported to another country without the permission of the right holder. Profits can be earned from the price differences between these two countries; thus parallel imports would cause damage to patent holder's capacity to differential pricing in different markets. In pharmaceutical markets, drug companies usually divide the markets by the territory of the nations, and adjust the prices of the same patented drug in different markets. Different price setting may be due to people's income standards, the amount of substitute, insurance coverage, manners of medical treatment or exchange rates. The validity of parallel imports depends on what kind of exhaustion principles to take - national exhaustion or international exhaustion. That is, if national exhaustion is adopted, parallel imports are not allowed. On the contrary, if international exhaustion is adopted, the patentee has no right to intervene in the parallel imports. However, the TRIPS Agreement does not directly regulate parallel imports. Article 6 of the TRIPS provides that, "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in

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<sup>66</sup> CARLOS M CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO, AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 75 (2000).

<sup>67</sup> Hestermeyer, *supra* note 5, at 229.

this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” It indicates that the adoption of a certain exhaustion principle is under the discretion of each Member. No matter which exhaustion principle is taken, other Members cannot argue that it is a violation of the TRIPS Agreement.

### B. Compulsory Licensing

Compulsory licenses are ones granted by the government after the completion of an administrative or judicial procedure, forcing a patentee to grant a license to third parties for the use of his patented product or process<sup>68</sup> to manufacture the generic drugs and thus creating competition.<sup>69</sup> Compulsory licenses can only be permitted to be used in the domestic market of the country that grants them, except for limited export.<sup>70</sup> As Article 31 of the TRIPS Agreement provided, “other use [than that permitted by Article 30 of the TRIPS Agreement] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.” It does not explicitly impose limitations for granting compulsory licenses so it becomes contentious as to under what kind of circumstances should the government grant compulsory licenses. Developing countries tended to confer its government broad discretion to grant compulsory licenses, whereas developed countries assumed a restrictive approach in the interpretation of the Agreement. The United States in the beginning even took a position of near-total ban on

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<sup>68</sup> Sterckx, *supra* note 22, at 187.

<sup>69</sup> Hestermeyer, *supra* note 5, at 239.

<sup>70</sup> See art. 31(f) TRIPS

granting compulsory licenses.<sup>71</sup> Nevertheless, compulsory licensing is an important method in accommodating access to medicine with the patent right system.

#### IV. Efforts in Reconciliation Between Public Health Needs and Patent Protection: The Doha Declaration

With the respect to the discussion of the difficulties experienced by developing countries in adopting the TRIPS flexibilities on pharmaceutical patents, although in the TRIPS flexibilities, the problem of access to medicine has been taken into account, the adoption of these flexibilities by Members who intend to make full use of these flexibilities still encounter many obstacles in practice, primarily because of the lack of legal security of the TRIPS flexibilities, lack of infrastructure in pharmaceutical industry, lack of corresponding legal and administrative supporting system, and pressure from industrialized countries with capacities to manufacture drugs.<sup>72</sup>

#### The Doha Declaration on the TRIPS Agreement and Public Health

A group of eighty countries drove for a legally binding declaration to read the TRIPS Agreement as

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<sup>71</sup> Hestermeyer, *supra* note 5, at 239.

<sup>72</sup> Take South Africa for example: Article 27(1) of the TRIPS Agreement was used against the government of South Africa in 2001 by the pharmaceutical multinationals, alleging that the South Africa's Medicine Act (1997), allowing the government to import generic versions of medicines which were still under patent protection in South Africa, violated the provision to protect their pharmaceutical patents. See *Pharmaceutical Manufacturers' Association of South Africa, et al. v. The President of the Republic of South Africa*, the Honourable Mr. N.R. Mandela N.O., et al., High Court of South Africa, Case number 4183/98. Ultimately, the companies withdrew the lawsuit.



allowing countries that seek to implement measures to promote access to affordable drugs do not have to fear retaliation by WTO or national governments. In 2001, WTO Members adopted the so-called Doha Declaration on the TRIPS Agreement and Public Health<sup>73</sup> in the 4<sup>th</sup> Session of the WTO Ministerial Conference, held at Doha, Quata. Some ambiguities between government's interest for public health and the interpretation of the flexibilities of the TRIPS Agreement were thus clarified in the Doha Declaration. It affirms that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and “the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” in the fourth paragraph. Responding to the developing countries’ concerns of the difficulties they faced in taking measures to facilitate access to medicines while acknowledging the purpose of intellectual property protection is “for the development of new medicines”.<sup>74</sup> Here I just list some important parts of the Doha Declaration relevant to the flexibilities of the TRIP Agreement. In its fifth paragraph, it states that:

- (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
- (c) Each Member has the right to determine what constitute a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. . .

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<sup>73</sup> WTO document WT/MIN(01)/DEC/1, November 20, 2001.

<sup>74</sup> WTO, the Doha Declaration, [http://www.who.int/medicines/areas/policy/doha\\_declaration/en/index.html](http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html)

Given the vague nature of the limitations for granting compulsory licenses in Article 31 of the TRIPS Agreement, and the pressures primarily from the U.S. under which developing countries encounter when planning to grant compulsory licenses, subparagraph (b) is very important to affirm a country's freedom to embed its national public health interests in its intellectual property protection system in order to achieve a balance between patent holder's rights and its obligations. In addition, the value of subparagraph (c) is that it emphasizes every member state's sovereign power to proclaim a (national) state of emergency,<sup>75</sup> and shift the burden of proof to the complaint party<sup>76</sup>.

Moreover, the sixth paragraph of the Doha Declaration addresses the problem that Members without sufficient pharmaceutical manufacturing capacities cannot make full use of compulsory licensing. It provides that:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

On August 30, 2003, the WTO General Council adopted an agreement on the implementation of paragraph six of the Doha Declaration. This agreement recognized a temporary waiver allowing countries

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<sup>75</sup> Sterckx, *supra* note 22, at 193-194.

<sup>76</sup> See CARLOS M CORREA, WHO, IMPLICATION OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 16-17 (2002).

producing patented drugs to export these products to eligible importing countries under certain conditions.<sup>77</sup>

However, these conditions appear to be burdensome for potential suppliers, and would discourage the use of such system. Thus, the agreement can hardly meet its purpose to provide an expeditious solution. In addition, only few countries, such as Norway, Canada, the EU, and India, have brought the waiver into their national laws.<sup>78</sup> This temporary waiver was then made permanent on December 6, 2006 as an amendment to the TRIPS Agreement. Once this amendment was ratified by two-thirds of WTO member states, it becomes part of TRIPS and comes into effect in those Members, replacing the 2003 waiver. The ratification deadline was originally set on December 1, 2007, but was extended to December 31, 2009 under a decision by the General Council on December 18, 2007.<sup>79</sup>

Generally, the Doha Declaration is applauded by the WTO Members and scholars for the efforts facing up to the conflicts between public health and the TRIPS Agreement and clarifying some ambiguities in the interpretation therein. However, the Doha Declaration still does not provide a comprehensive resolution to the uncertain role of access to medicine in the WTO system, and the insecurity in the interpretation of the TRIP Agreement remains.<sup>80</sup>

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<sup>77</sup> The conditions should be examined step by step: an entity in the importing country must first seek a voluntary license from the patent holder; if efforts to obtain a voluntary license fail, a compulsory must be applied for and obtained in the importing country; the importing country, unless it is a Least Developed Country, must show that it has insufficient capacity to produce the drug locally; the importing country must notify the TRIPS Council that it has decided to use paragraph 6; the interested importing country or entity must identify a potential exporter; the potential exporter must first try to obtain a voluntary license on commercially reasonable terms for a commercially reasonable period of time etc. for more complete picture of the conditions imposed, *See Sterckx, supra* note 22, at 195-196.

<sup>78</sup> *Id.*

<sup>79</sup> *See* WTO, TRIPS: TRIPS and Public Health, Members accepting amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

<sup>80</sup> Hestermeyer, *supra* note 5, at 261.

## V. Human Right Analysis of Access to Medicine

### 1. International Human Rights Relevant to Access to Medicine

In determining the relationship between two regimes – human rights and intellectual property – under the framework of international human rights analysis, there are two different approaches:<sup>81</sup> the first regards these human rights and intellectual property fundamentally conflict with each other. When strong intellectual property protection has undermined human rights, particularly in the area of economic, social, and cultural rights, they are incompatible. In short, human rights law is superior to intellectual property law when they confronted with each other. The second approach views both areas of laws as essentially compatible, provided that their scopes are appropriately defined. It is possible to strike a balance between the two regimes. In this study, I will engage in the second approach, allowing the adjustment of scopes of the rights because it is contributive to our understanding of both rights through the process of reconciliation.

Under the framework of international human rights law, I will first walk through several sources of international law affirmed under the United Nations regime, holding that they have become customary international law; thus they are legally binding to all nations,<sup>82</sup> including the WTO Members. Human rights relevant to access to medicine primarily involve the right to health, the right to life, and the right to enjoy the

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<sup>81</sup> Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 Minn. Intell. Prop. Rev. 47, 48 (2003).

<sup>82</sup> Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean For Our Nation and World?*, 34 Ind. L. Rev. 1457, 1464 (2001).

benefits of scientific progress as we will discuss in the following paragraphs.

### A. The Right to Health

Not until post-World War II did the concept of a human right to health began to develop. The WHO, a specialized agency in the United Nations, directing and coordinating global health matters, was set up in 1948. The Constitution of the WHO is the first international legal acknowledgement explicitly covering the right to the “enjoyment of the highest attainable standard of health.”<sup>83</sup> To date, the access to medicine has been recognized by several sources of international law, including treaty law and international law.<sup>84</sup> There are two major international human rights Covenants regarding the protection of access to medicine – International Covenant on Civil and Political Rights<sup>85</sup> (the ICCPR), protecting access to life-saving medicine, and the International Covenant for Economic, Social and Cultural Rights (the ICESCR) protecting access to essential medicine.

Access to medicine is contained in Article 12 of ICESCR as an integral part of the right to health, which reads:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
  - (a) The provision for the reduction of the stillbirth-rate and of infant mortality

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<sup>83</sup> Hestermeyer, *supra* note 5, at 84.

<sup>84</sup> *Id.* at xxxv.

<sup>85</sup> International Covenant on Civil and Political Rights, adopted Dec. 19, 1966, S. Exec. Doc.

and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

In Article 2(1) of the ICESCR, States Parties are under obligations to live up to the goals set above:

Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.

Therefore, the standard of the right to health includes “a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment,” not limiting to the right to health care.<sup>86</sup> In pursuing other socio-economic rights, the right to health care, including the medicine, is most fundamental in the “dignity and worth of the human person” in which human rights are based on. At the present time, medication is playing a vital and indispensable role in preventing, controlling, and treating diseases. Thus, the right to medicine is embraced in the right to health in order to reach individual’s “highest attainable standard of physical and mental health.” Several countries also have had chance to clarify through adjudication that the

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<sup>86</sup> Committee on Economic, Social and Cultural Rights, *General Comment No 14* (2000), para 4.

accessibility of medicine is part of the right to health.<sup>87</sup> In the CESCR General Comment No 14,<sup>88</sup> it has been stated that the right to health contains four interrelated dimensions: the availability of sufficient quantity of medicines, the accessibility to treatment of all groups of populations without discrimination, the acceptability of treatment being ethically and culturally appropriate, and the scientifically appropriate quality of medicine. These four elements serve as indicators of State Parties' success to achieve the right to health. Among these four dimensions, the economic accessibility of medicine is essential and States are obligated to provide such accessibility.

### B. The Right to Life

Many epidemics have high mortality rates. Human health is acutely threatened if appropriate pharmaceuticals are not provided in time. The realization of the right to life is the premise of other human rights. In Article 3 of the Universal Declaration of Human Rights, it provides that, "Everyone has right to life, liberty and security of person."<sup>89</sup> And in Article 6.1 of the ICCPR, "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life" also contains protection of the right to life.

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<sup>87</sup> The Constitutional Court in South Africa has recognized the access to medicine in the South African Constitution. See *Minister of Health et al v. Treatment Action Campaign et al.* (2002).

<sup>88</sup> WTO, *supra* note 79, at para 12.

<sup>89</sup> Universal Declaration of Human Rights, G.A. Res. 217A(III), U.N. GAOR, 3d Sess., at 71, U.N. Doc. A/810 (1948).

### C. The Right to Enjoy the Benefits of Scientific Progress

According to Article 15(1)(b) of the ICESCR: “The States Parties to the present Covenant recognize the right of everyone: (b) To enjoy the benefits of scientific progress and its applications.”

Scientific progress and its applications include “existing tools, interventions and knowledge as well as those that do not yet exist.”<sup>90</sup> It is no doubt that new drugs are under the catalog of scientific progress; thus access to medicine is protected as significant human right. States Parties are under obligation of Article 15(2) to take steps to realize this human right. However, in Article 15(1)(c), individuals have the right to “benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” Hence, there is a debate over whether intellectual property rights are included in Article 15(1)(c).<sup>91</sup> In any event, even if accepting the argument that intellectual property rights is encompassed, since these two rights are co-exist in Article 15, a balance should be stricken, and there is no implication that intellectual property rights should outweigh the right to health.

### 2. Solving the Conflict Between Intellectual Property Rights and Human Right of Access to Medicine

In this section, I am going to argue in favor of the right to access to medicine when public health emergencies emerge in a country and the drug patent holder’s right should yield.

First, the Committee on Economic, Social and Cultural Rights published a statement on human rights

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<sup>90</sup> Smith, *supra* note 12, at 60.

<sup>91</sup> *Id.*, at 59-60.



and intellectual property rights in 2000, making the distinction between human rights and intellectual property rights and clarifying that treaties, including the TRIPS Agreement, should be implemented consistently with international human rights law. It has been noted by the Committee that “human rights are fundamental, inalienable and universal entitlements belonging to individuals,” compared to “intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits”<sup>92</sup> From the historical perspective of patent development discussed in Part III, we have become aware that patent granting is not an absolute right, and its grant is under discretion of the national authorities served as a mechanism for the encouragement of scientific progress. The ultimate purpose of scientific advancement is for the welfare of human being. On the contrary, access to medicine is in the core component of the human right to health. It has been universally acknowledged for states to be obligated to fully realize this human right.

Therefore, in my opinion, patent protection for pharmaceutical products as an instrumental tool should ultimately serve the fundamental goal of human rights protection, the social good, through efficient application of the flexibilities provided by existing WTO regime in the face of national public health emergency. Otherwise, the over emphasis on patent protection, in the negligent of its purpose to facilitate human health, overlooks the essential value of the grant of patent protection. Merely the incentive function of patents cannot justify the opposition measures taken by some pharmaceutical companies in the industrialized countries

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<sup>92</sup> CESCR, Statement by the Committee on Economic, Social and Cultural Rights; See also *Id.*

against compulsory licensing in developing countries. “An interference with access to today’s medicine with the protection of access to tomorrow’s medicine”<sup>93</sup> cannot serve as an equivalent argument against people in desperate need for medicine in developing countries. Mental and physical health is the basis of the development of human dignity; it is the obligation of the government not to intrude on individual health and also actively to respect, to protect and fulfill the integrity of individual’s right to health.

Secondly, given the dual character of pharmaceutical products<sup>94</sup> - ordinarily as commodities advancing people’s lives but sometimes working as the most basic, even life-saving, dimension improving the quality of lives, these products cannot be treated as merely ordinary commodities. Unlike those ordinary commodities which stress the value of free market, medicine’s public interest peculiarity and its direct influence to human health, often shown in the national public health crisis, has bestowed itself to more intervention of national regulatory power to ensure access to medicine. When private market has proven to fail in its major function of efficiency and cannot properly distribute essential resources to the people in need, it is the time for public mechanism to intervene. Weaker patent protection in the face of national emergency or other circumstances of extreme emergency is thus justified. However, letting the government be the only institution to shoulder all the responsibilities of improving access to medicines is not always efficient. We will discuss other alternatives in the next section.

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<sup>93</sup> Hestermeyer, *supra* note 5, at 297

<sup>94</sup> Smith, *Supra* note 12, at 48.

### 3. Possible Solutions to Improve Access to Medicine

#### A. Importing Human Rights Considerations into the WTO Law and Beyond

The conflict between the TRIPS Agreement and access to medicine is substantially a conflict between the world trade regime and the human rights regime. On account of the WTO regime's strong and effective enforcement mechanism, it is on a higher level in a factual hierarchy; whereas the human rights regime has a relatively weaker enforcement system despite its higher normative appeal than the WTO regime. Consequently, in practice, states are more likely to comply with the dispute solutions within the WTO rather than abide by human rights requirements. Therefore, it is important to accommodate human rights law with the WTO system, and the only solution to secure the access to medicine whenever conflict happens is by conferring human rights law a stronger status within the WTO system.<sup>95</sup>

In the efforts to import human rights considerations into WTO law, it can be first done through taking the right to access to medicine, which is under the ICESCR, ICCPR and general international law, into account in the interpretation of the existing flexibilities of the TRIPS Agreement. Moreover, the Appellate Body can import human rights to medicine in public health threats as a broad, modern definition of "security" in accordance with Article 73 of the TRIPS Agreement,<sup>96</sup> allowing Members to prioritize the necessary

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<sup>95</sup> Hestermeyer, *supra* note 5, at 182-206, 302.

<sup>96</sup> Article 73 provides, "Nothing in this Agreement shall be construed: (a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests; (i) relating to fissionable materials or the materials from which they are derived; (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; (iii) taken in time of war or other emergency in international relations; or (c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security."

treatment of pandemics for the protection of its essential security interests.

Secondly, through the amendment to the WTO Agreements to accommodate human rights, a separate WTO human rights treaty can be enacted or referred to the ICESCR or the ICCPR.<sup>97</sup>

The third option is through either cooperative arrangement or informal cooperation between the WTO and other human rights related organizations, to encourage cross influence and mutual understanding.<sup>98</sup>

However, the challenges are that, beyond the WTO system, many developed countries, in particular the United States, now seek their negotiation field to free trade agreements and bilateral investment treaties to include intellectual property rights that may have the effect of limiting TRIPS flexibilities or imposing additional obligations as these agreements are interpreted independently of the TRIPS Agreement. This potential conflict may be solved by reading the term “intellectual property” in these agreements or treaties as reference to the intellectual property rights defined in the TRIPS Agreement.<sup>99</sup>

#### B. Technology Transfer to Developing Countries

Once the manufacturing capacity of pharmaceuticals has been established, it can benefit the state economy as well as enable the government to make full use of its compulsory licensing system to deal with public health crises. Therefore, in order to solve the problem of access to medicine in developing countries,

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<sup>97</sup> *Id.* at 287.

<sup>98</sup> *Id.* at 287-288.

<sup>99</sup> Hestermeyer, *supra* note 5, at 291.

building up the local manufacturing capacity of pharmaceuticals is a better solution in the long run. However, pharmaceutical industry requires high technology intensity; hence, short of technology transfer, the manufacturing capacity is difficult to build by developing country itself. In accordance with Article 7 of the TRIPS Agreement, which provides that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations,” and Article 66(2), which provides that “developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.” Technology transfer is within the objectives of the intellectual property rights and developed countries are obligated to live up to the goal.

However, the least-developed countries have complained that the commitment to technology transfer is not carried out by developed countries<sup>100</sup> What’s worse, the importation of highly competitive intellectual property-intensive products has the negative effect of forcing local manufacturers out of the market.<sup>101</sup> Even though the Doha Declaration has reaffirmed the developed countries’ obligation under Article 66 (2) of a Working Group on Trade and Transfer of Technology to be set up, the goal of technology transfer to less industrialized countries has not been accomplished. In the international trading regime, “some highly

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<sup>100</sup> Correa, *supra* note 78, at 35.

<sup>101</sup> Rochelle Cooper Dreyfuss, *TRIPS-Round II: Should Users Strike Back?*, 71 U. Chi. L. Rev. 22, 29 (2004).

vulnerable members of the WTO [has been disempowered] from the benefits of a liberal trading order by loading them with undue burdens for commitments made by participating in the regime. The most damning indictment against the international trading regime is that it formally entrenches uneven consequences for developing and developed countries.”<sup>102</sup> The benefits and burdens of international trade should be proportionately allocated to developing countries. Thus, given that the obligation regulation of technology transfer in Article 66(2) of the TRIPS Agreement is relatively rough compared to other denser regulation protecting intellectual property right, the WTO should reexamine its regulation as well as implementation on the transfer of pharmaceutical technology.

C. WIPO Should Be Responsible for Assisting Developing Countries with Bringing the Flexibilities  
into Legislation

The legislation of many developing countries has not yet included the mechanism of flexibilities of the TRIPS Agreement, and this is partly due to their lack of ability to enact related laws that are helpful in resolving the problem of access to medicine. Since the duties of the WIPO involve assisting Members to establish intellectual property law, it should be responsible for providing assistance to developing countries, enacting laws that are in consistent to the flexibilities of the TRIPS Agreement, the Doha Declaration, and their

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<sup>102</sup> James Gathii, *Fairness as Fidelity to Making the WTO Fully Responsive to All Its Members*, 97 Am. Soc'y Int'l L. Proc. 157, 167 (2003).

national interest.<sup>103</sup>

#### D. A Critical Role of Non-state Actors

Since the dual character of medicine as a commodity on one hand and as a product vital to human health on the other, and the fact that the privately owned pharmaceutical industry has long dominated the creation and manufacture of drugs, despite public funding to research, a tension has arisen between the state authority and private entities. Yet the dual character of medicine makes it so that these manufacturers cannot shirk their responsibility when their product appears vital to human health. Because of their enormous impact on the lives of individuals, the pharmaceutical industry should be held accountable.<sup>104</sup>

In addition to relying on the government to carry out the task of providing access to medicine, non-state actors, such as non-governmental organizations, communities, pharmaceutical companies and health professionals sometimes are more efficient and capable than governments in taking responsibilities to respect, protect and fulfill the right to health.<sup>105</sup> Moreover, civil society groups can put pressure to the governments to realize their obligations under human rights law. They are also capable of bringing in potential human rights concerns, working at the grass-root level and suggesting possible remedies.<sup>106</sup> With an increasing role of these non-state actors, human rights are better served.

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<sup>103</sup> Lei, *Supra* note 17, at 196-197.

<sup>104</sup> Smith, *Supra* note 12, at 65.

<sup>105</sup> *Id.*, at 49, 66.

<sup>106</sup> *Id.*, at 68-70.

### E. Incentives of Pharmaceutical Manufacturers

The objection of the pharmaceutical industry to the grant of compulsory licensing, for instance, is because strong patent protection, allowing them to set high prices on the market without fear of being undercut by competitors, provides an indispensable incentive for research and development for invention. However, in my opinion, strong patent protection only provides a manner of incentive for invention, for its function to guarantee monopoly pricing as a return for pharmaceutical companies' great investment on research and development. Thus, this monetary incentive for innovation can also be achieved by other means of subsidizing the potential patent holder, that is, to ensure enough money would be made. Though it cannot be denied that strong patent protection is the utmost way for pharmaceutical industry to make profits, it should be recognized that due to this industry's product that has vital impact on human health and its social responsibility to human rights, the companies should make a concession to less profit when the loss of profit serves for people desperate in need provided that the flexibilities are soundly implemented. This potential profit loss should be considered expected and thus included in the company's policy making. After all, the ultimate purpose of the invention of pharmaceuticals is for technology advancement and for further human health.

Therefore, if other fund resources are ensured, they can also serve as incentives for the pharmaceutical's invention to assure wide access to pharmaceuticals when they are developed. Possible solutions to provide incentive are by investing government fund or grant in desired research or by some other institution's



commitment to fully or partially finance purchase before drugs have been developed.<sup>107</sup>

#### F. Creating an Environment Favorable for Differential Pricing

Pharmaceutical companies' policy to engage in differential pricing is able to serve the need of people in developing countries for lower priced drugs in response to their small buying power while the pharmaceutical companies make profit. Therefore it contributes to resolving the problem of access to medicine in developing countries. However, the major difficulties in implementation of differential pricing are, first, fail to distinguish markets charging different prices, and the drugs in low prices are circulated to other markets, thereby reducing pharmaceutical companies' profit in other markets; second, people in developed countries are reluctant to pay for higher prices, stressing pharmaceutical companies to drop drug prices according to their price in developing countries.<sup>108</sup> In removing these obstacles to create an environment favorable for adopting differential pricing, developing countries may adopt national exhaustion to stop parallel imports that serves both its interests and that of drug companies. Although under the TRIPS Agreement and the Doha Declaration, states are free to decide which exhaustion principle to take. Furthermore, in view of duly contribution of resources worldwide, it may be appropriate for developed countries to pay higher price for drugs than so as to compensate for the cost of research an development, and to encourage differential pricing

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<sup>107</sup> See MICHAEL KREMER AND RACHEL GLENNERSTER, *STRONG MEDICINE: CREATING INCENTIVES FOR PHARMACEUTICAL RESEARCH ON NEGLECTED DISEASES* (2004).

<sup>108</sup> *Id.* at 201.

in developing countries.<sup>109</sup>

## VI. Conclusion

Many epidemics are curable or manageable, but the treatments are sometimes unaffordable to people in the developing world. People die from having no access to medicines, which deteriorates the development of these less-industrialized countries. After the TRIPS Agreement was brought into force, developing countries in most circumstances can no longer depend on generic drugs; thus, access to medicine become even more limited. To solve the controversy in interpreting the TRIPS Agreement and the generated public health crises, the Doha Declaration was adopted. In the Doha Declaration, the flexibilities of the TRIPS Agreement are recognized as effective and vital manners to promote access to medicines. That is, in certain emergency circumstances, public health needs can outweigh the right of pharmaceutical patent holders. The same conclusion can be drawn from the examination of international human rights law.

In order to accommodate the public health needs, in particular the access to medicine, this paper suggests a flexible intellectual property regime – taking human rights concerns in interpreting the TRIPS Agreement or adopting amendments relevant to accessibility of medicine to other WTO Agreements. It can also be achieved by the WTO's cooperation with other human rights related organizations or through importation of the definition of "intellectual property" in the TRIPS Agreement to other free trade agreements

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<sup>109</sup> Eric Reinhardt, *Intellectual Property Protection and Public Health in the Developing World*, 17 Emory Int'l L. Rev. 475, 486-487 (2003).

and bilateral investment treaties.

Furthermore, the goal of transferring technology to developing countries set in the Article 7 and 66 (2) of the TRIPS Agreement should be put into practice. WIPO should be responsible for providing assistance to developing countries to adopt the flexibilities into their legislation based on their specific needs.

In addition, non-state actors, including pharmaceutical companies, also play an increasingly critical role in promoting the right to health. The incentives for innovation cannot only be provided by patent while the industry recognizes its responsibility in public health crises and makes concession to its maximum profit made through monopoly pricing. Other public or private fund resources can all be served for incentives for invention. Moreover, the willingness of pharmaceutical companies to engage in differential pricing contributes to the solution for the access to medicine. Thus, it is important for developing countries to create an environment beneficial for differential pricing.

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